Section 5: 510(k) Summary

This 510(k) summary has been prepared in accordance with 21 CFR 807.87(h) and the 510(k) has been prepared in accordance with 21 CFR 807.92

Submitter

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Date Summary Prepared

October 29, 2013

Device Trade Name

Ambu® aScope™ 3 5.0/2.2
Ambu® aScope™ 3 Slim 3.8/1.2
Ambu® aView™ Monitor

Device Common Name

Flexible Bronchoscope

Device Classification

Bronchoscope (flexible or rigid) and accessories
Product Codes: EOQ
21 CFR 874.4680
Class II

Legally Marketed devices to which the device is substantially equivalent

	Manufacturer	Trade Name	510k number
A:	Olympus Corporation	Olympus BF Type 160 Video Bronchoscope	K023984
B:	Olympus Corporation	Olympus LF-TP Tracheal Intubation Fiberscope	K981543
C:	Olympus Corporation	Olympus LF-DP Tracheal Intubation Fiberscope	K981543
D:	Vision Sciences	BRS-5000 Flexible Digital Video Bronchoscope	K091768
E:	Ambu A/S	Ambu aScope 2 and Ambu aScope Monitor	K110962

Description of the Device

The system consists of Ambu aScope 3 (Ambu aScope 3 5.0/2.2 or Ambu aScope 3 Slim 3.8/1.2) and Ambu aView Monitor.

Ambu aScope 3 has been designed for airway management within the larynx and the tracheobronchial tree. This includes endoscopic observation to assess airway anatomy, endotracheal/endobronchial intubation and management. Ambu aScope 3 is for single use and it is sterile.

The Ambu aScope 3 must be connected to Ambu aView Monitor. The monitor displays the image and it is reusable.

Ambu aScope 3 has the following physical and performance characteristics:

- Maneuverable tip controlled by the clinician
- Flexible insertion cord
- Camera and LED light source at the distal tip
- Working channel
- Sterile by Ethylene Oxide sterilization
- For Single Use

The differences between Ambu aScope 3 5.0/2.2 and Ambu aScope 3 Slim 3.8/1.2 are as follows:

- Distal end outer diameter
- Insertion tube outer diameter
- Working channel inner diameter
- Angulation range

Ambu aView Monitor has the following physical and performance characteristics:

- Displays the image from Ambu aScope on the screen.
- Can record snapshot or video of image from aScope
- Can be fixed to e.g. an IV pole.
- Reusable device.

Indications for Use

The aScope 3 endoscopes have been designed to be used with the aView monitor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

The aScope 3 system is for use in a hospital environment.

The aScope 3 is a single-use device designed for use in adults. It has been clinically evaluated for the following minimum endotracheal tubes
(ETT) and double lumen tubes (DLT) sizes:

Scope	Minimum ETT inner diameter	Minimum DLT size
aScope 3 Slim 3.8/1.2	5.0mm	37Fr
aScope 3 5.0/2.2	6.0mm	41Fr

Endoscopic accessories designed for a minimum working channel width up to 2.0mm can be used with the aScope 3-5.
Endoscopic accessories designed for a minimum working channel width up to 1.2mm can be used with the aScope 3-Slim.

Summary of the technological characteristics in comparison to the predicate devices

The Ambu aScope 3 System, consisting of Ambu aScope 3 and Ambu aView Monitor, is similar to the predicate devices in the following areas:

- They are all flexible endoscopes with a maneuverable tip
- Predicate D and E are single-use devices, which are delivered sterile
- Predicate D and E use a LED-light source located at the tip of the scopes
- Predicate A, D and E possess a camera located at the distal tip to provide an image
- They all have a handle with a control button giving the operator the ability to steer the tip of the scope up and down
- All devices can display an image on a separate monitor
- Predicate device A, B, C, and D possess a suction port equivalent to aScope 3
- The aScope 3 's inner and outer diameters are within the same range as the predicate devices

Furthermore, Ambu aView Monitor is equivalent to aScope monitor, predicate E, on the following parameters:

- Both display a live image on a TFT-screen
- Power is supplied to the endoscope via the connection to the monitor
- Both are powered by a rechargeable battery or a power supply
- Both systems can be operated either on battery or on mains power
- Both monitors are portable

Ambu concludes that the Ambu aScope 3 and Ambu aView Monitor is substantially equivalent to the predicate devices.

Performance Data - Bench

The following data has been submitted in the premarket notification:

Ambu has provided declaration of conformity to the following recognized consensus standards applicable for this type of device:
- ISO 8600-1, ISO 8600-3 and ISO 8600-4 Optics and optical instruments – medical endoscopes and certain accessories.
- ISO 594-1 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment.

The declaration of conformity is based on test data.
Result: All tests were passed.

Performance test report was submitted to document the following properties of the Ambu aScope 3 (single use):
- Bending angle and endurance of the bending section (accept criteria: bending to the maximum bending angle aScope 3 Slim 3.8/1.2; 130° up and down, aScope 3 5.0/2.2; 130° down and 150° up)

Result: All tests were passed.

Performance test report was submitted to document the following properties of the Ambu aView Monitor (reusable):
- Imaging performance; evaluation of colors, flickering, contrast and haze, rated on a scale from 1-3, where 1 is best. (accept

criteria: rating 1 and with a maximum of two ratings of 2)
- Chemical endurance of Ambu aView Monitor (accept criteria: monitor can withstand the chemicals in contact with the monitor including cleaning and disinfection chemicals for reprocessing)
- Battery capacity of Ambu aView Monitor (accept criteria: at least 70% battery capacity after 150 charging cycles)

Result: All tests were passed.

Performance test report was submitted to document Shelf life of Ambu aScope 3. Testing was done on finished, sterilized, shipped and aged products:
- Performance test of the Ambu aScope 3. Test according to Final Quality Inspection Procedure of Ambu aScope 3.
  Accept criteria: Product specifications fulfilled
- Sterile packaging integrity of the Ambu aScope 3 pouch.
  Accept criteria: The seal strength must be greater than 0.4 N when tested according to ASTM F88.

Result: All tests were passed

Since the device is in compliance with the listed standards and has passed the listed performance tests, it is concluded that technological characteristics of Ambu aScope 3 and Ambu aView Monitor is as safe and effective and performs as well as or better than the chosen legally marketed predicate devices.

Environmental tests performed on aScope 3 5.0/2.2, aScope 3 Slim 3.8/1.2 and aView Monitor to demonstrate the compliance to the following standards:
Transportation in designated packaging:

- EN 60068-2-27 Basic environmental testing procedures - Part 2: Tests - Test Ea and guidance: Shock: 500 repetitive shocks (bump) in each of 6 directions 400 m/s2 (40g)
- EN 60068-2-64 Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance: Random vibration 1.6 grms, 10-150Hz, 30 min/axis
- EN 60068-2-31 Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens: 12 falls from 1.2m height

Tests performed with the product without its packaging:
Bounce

- EN 60608-2-6 Environmental testing - Part 2-6: Tests - Test Fc: Vibration (sinusoidal): Sinus vibration 5Hz, 1grms, 1 hour.

Free fall

- EN 60068-2-31 Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens:
  Ambu aScope 3: 2 falls per relevant orientation from 1.2m height to a smooth concrete surface.

After each of the above environmental tests, the packaging integrity and the device were inspected, and performance test of the device was performed.
Result: All products and packaging passed the tests.

Based on the above environmental testing Ambu has concluded that Ambu aScope 3 and Ambu aView Monitor, can withstand the stresses applied to the product during transport and handling prior to the use of the device, and is as safe and effective and performs as well as or better than the chosen legally marketed predicate device.

	Data for compliance to the general requirements for the device were submitted: Biocompatibility tests shows that the device complies with the requirements of ISO 10993-1: - Cytotoxicity (ISO 10993-5) - Ethylene oxide sterilization residuals (ISO 10993-7) - Sensitization (ISO 10993-10) - Intracutaneous reactivity test (ISO 10993-10) Result: All tests were passed. Tests that verify the following properties: - Cleaning validation and Liquid Chemical Sterilization and Disinfection Validation of the Ambu aView Monitor according to AAMI TIR12 and AAMI TIR30, to validate the prescribed method of cleaning and disinfection. - Electro Magnetic Compatibility in compliance with IEC 60601-1-2. - Electrical Safety in compliance with IEC 60601-1 and IEC 60601-2-18. Result: All tests were passed. Since the device passed all the tests to demonstrate compliance to the general requirements for this kind of device, it is concluded that Ambu aScope 3 and Ambu aView monitor is as safe and effective and performs as well as or better than the chosen legally marketed predicate devices.
Performance Data - Clinical	Not applicable.
Conclusion	Based on the indication for use, technological characteristics, performance data and comparison to predicate devices it has been concluded that the functionality and intended use of Ambu aScope 3 and Ambu aView Monitor is equivalent to the predicate devices. It is concluded that Ambu aScope 3 and Ambu aView Monitor are as safe and effective and perform as well as or better than the chosen legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 1, 2013

Ambu A/S
c/o Mr. Sanjay Parikh
VP Operations
6740 Baymeadow Dr.
Glen Burnie, MD 21060

Re: K130845
Trade/Device Name: Ambu® aScope™ 3 5.0/2.2, Ambu® aScope™ 3 Slim 3.8/1.2, Ambu® aView™ Monitor
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid)
Regulatory Class: Class II
Product Code: EOQ
Dated: September 27, 2013
Received: September 30, 2013

Dear Mr. Parikh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130845

Device Name: Ambu® aScope™ 3 5.0/2.2
Ambu® aScope™ 3 Slim 3.8/1.2
Ambu® aView™

Indications For Use:

The aScope 3 endoscopes have been designed to be used with the aView monitor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

The aScope 3 system is for use in a hospital environment.

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Sunny Park